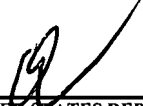




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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,859	07/30/2003	Gary F. Gerard	IVGN 338	6152

65482 7590 10/30/2007  
INVITROGEN CORPORATION  
C/O INTELLEVATE  
P.O. BOX 52050  
MINNEAPOLIS, MN 55402

EXAMINER

BURKHART, MICHAEL D

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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10/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/629,859

Applicant(s)

GERARD, GARY F.

Examiner

Michael D. Burkhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9, 12-14, 17, 19-21 and 26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 12-14, 17, 19-21 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/2007 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 12-14, 17, 19-21 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Rothenberg et al (J. Virol., 1974) as evidenced by Murray et al (Medical Microbiology, 1998). **This rejection is maintained for reasons made of record in the Office Action dated 7/11/2007, and for reasons set forth below.**

### ***Response to Arguments***

Applicant's arguments filed 10/11/2007 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) Rothenberg et al do not teach a purified polypeptide having reverse-transcriptase activity, but rather teach the use of detergent-disrupted

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virions, which comprise elements other than reverse transcriptase, such as viral glycoproteins, etc.; 2) the virion preparations of Rothenberg et al might also contain  $Mg^{2+}$ , thus, the total amount of  $Mg^{2+}$  in the reactions of Rothenberg et al may exceed the total amount of dNTPs.

Regarding 1), the virions used by Rothenberg et al, and hence the reverse transcriptase contained within the virions, were purified from NIH3T3 cells by isopycnic banding of the virions. See page 168, second column, first full ¶ of Rothenberg et al, and the method referenced therein, found on page 168 of Rothenberg et al (J. Virol., 1976). Thus, absent a definition of a "purified" polypeptide having reverse-transcriptase activity in the specification, the term is interpreted broadly to include purification of the reverse transcriptase enzyme from the NIH3T3 cells by isopycnic banding of the virions. This represents a great level of purification relative to the number and amount of contaminants (e.g. host cell membrane components, host nucleic acids, cellular proteins) that are present prior to purification of the virions from the host cell. Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., purification of reverse transcriptase away from other viral components, such as viral glycoproteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding 2), a review of the prior art of record reveals no mention of  $Mg^{2+}$  in the virion preparations. It is thus unclear from where applicant believes such free  $Mg^{2+}$  may be coming from. Absent any reasoning or evidence as to why the purified virions would comprise  $Mg^{2+}$ , and in sufficient amounts (e.g. 6 mM) to offset the  $Mg^{2+}$ /dNTP concentration differential taught

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by Rothenberg et al, the rejection stands. "Argument of counsel cannot take the place of evidence lacking in the record." *In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974).

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The cDNA and nucleic acid molecules of the claims are not recited as isolated or purified, and thus read on a product of nature. It is noted that the claims are product by process claims, but are not limited by the process steps, only the structure implied by the steps. See MPEP §2113. As such, the claims encompass cDNA and nucleic acid made, for example, by a retrovirus upon infection of a host cell.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhardt whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

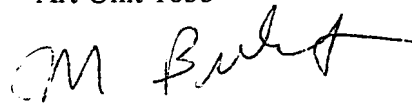
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart

Examiner

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A handwritten signature in black ink, appearing to read "M Burkhart", is written over the printed name and title.